The opinion in support of the decision being entered today was **not** written for publication and is **not** binding precedent of the Board.

Paper No. 36

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte STEVEN R. GOLDSTEIN and RODNEY W. BOSLEY, JR.

Appeal No. 2001-0547 Application No. 08/689,400

HEARD: February 4, 2003

Before ABRAMS, FRANKFORT, and NASE, <u>Administrative Patent Judges</u>. ABRAMS, <u>Administrative Patent Judge</u>.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1-6, 8-12 and 17-28. Claim 7 has been canceled, and claims 13-16 and 29-33 have been withdrawn from consideration as being directed to a non-elected invention.

We REVERSE.

BACKGROUND

The appellants' invention relates to a device for infusing fluid into the uterine cavity. An understanding of the invention can be derived from a reading of exemplary claim 1, which appears in the appendix to the Brief.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Meador	4,071,027	Jan. 31, 1978
Harris	4,430,076	Feb. 7, 1984
Weber	5,147,315	Sep. 15, 1992
Swor	5,364,375	Nov. 15, 1994
Nicholas	5,431,662	Jul. 11, 1995

The examiner has set forth the following rejections:

- (1) Claims 1-6, 8-12 and 17 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.
- (2) Claims 18, 19, 22, 23 and 26 under 35 U.S.C. § 102(b) as being anticipated by Nicholas.
- (3) Claims 1, 5, 6 and 8-11 under 35 U.S.C. § 103(a) on the basis of Nicholas in view of Meador.
- (4) Claims 1, 2 and 4 under 35 U.S.C. § 103(a) on the basis of Swor in view of Meador.
- (5) Claim 3 under 35 U.S.C. § 103(a) on the basis of Swor in view of Meador.
- (6) Claim 20 under 35 U.S.C. § 103(a) on the basis of Nicholas.
- (7) Claim 21 under 35 U.S.C. § 103(a) on the basis of Nicholas in view of Swor.
- (8) Claim 24 under 35 U.S.C. § 103(a) on the basis of Nicholas in view of Weber.

- (9) Claim 25 under 35 U.S.C. § 103(a) on the basis of Nicholas in view of Harris.
- (10) Claim 27 under 35 U.S.C. § 103(a) on the basis of Nicholas.
- (11) Claim 28 under 35 U.S.C. § 103(a) on the basis of Nicholas.
- (12) Claim 12 under 35 U.S.C. § 103(a) on the basis of Nicholas in view of Meador.
- (13) Claim 17 under 35 U.S.C. § 103(a) on the basis of Nicholas in view of Meador.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the above-noted rejections, we make reference to the Answer (Paper No. 23) for the examiner's complete reasoning in support of the rejections, and to the Brief (Paper No. 22) and Reply Brief (Paper No. 29) for the appellants' arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by the appellants and the examiner. As a consequence of our review, we make the determinations which follow.

The Rejection Under The First Paragraph Of Section 112

The examiner has rejected claims 1-6, 8-12 and 17 under the first paragraph of Section 112 because the specification does not explain how the one-way valve recited in these claims is used to avoid air bubbles. The appellants argue in rebuttal that this valve is described in their specification to such an extent as to allow one of ordinary skill

in the art to make and use the invention, which is all that is required under this section of the statute. They further point out that the statement in the claim "to avoid producing air bubbles" would be understood by one of ordinary skill in the art to mean that the one-way valve is installed in such a manner as to preclude air bubbles from being produced during the operation of the device, that is, so oriented as to permit flow in the direction in which bubbles are not produced, which is into the distal end of the elongated tubular body.

The examiner has not explained why the presence of the disputed phrase in the claims would cause one of ordinary skill in the art not to be enabled to make and use the invention. It is our view that the specification describes the invention in such a manner as to meet the requirements of the first paragraph of Section 112. This being the case, we agree with the appellants that there is no basis for the rejection, and we will not sustain it.

The Rejection Under Section 102

Claims 18, 19, 22, 23 and 26 stand rejected as being anticipated by Nicholas.

Anticipation is established only when a single prior art reference discloses, either expressly or under the principles of inherency, each and every element of the claimed invention. See In re Paulsen, 30 F.3d 1475, 1480-1481, 31 USPQ2d 1671, 1675 (Fed. Cir. 1994) and In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990).

Nicholas is directed to a surgical apparatus for manipulating body tissue in the uterine cavity. In the embodiment shown in Figure 18, to which the examiner has referred (Answer, page 5), Nicholas discloses an elongated tubular body 272 having a central passage with an opening at the proximal end to allow fluid to be delivered and an opening at the distal end to allow fluid to be discharged (column 9, lines 14-21). A conical cervical seal 222 is slidable along the tubular body, and an elongated handle 212 is provided at the proximal end of the tube to allow the device to be manipulated.

However, Nicholas does not disclose or teach two of the limitations recited in independent claim 18. The first is that the cervical seal be "slidable along the entire length of the tubular body." In the Nicholas device, the proximal portion of the tube passes through handle 212, that is, the handle surrounds the tube, and thus precludes the cervical seal from sliding along the entire length of the tube. The second deficiency is the requirement that the cervical seal have "a neck at the distal end of said seal engaging the elongated body to avoid any leakage" at the interface of these two elements. While there appears to be a neck on the proximal end of the Nicholas seal as shown in Figure 13B, no description of this element is provided and, of course, it is not located at the distal end of the seal and therefore doesn't meet the terms of the claim.

Since all of the elements recited in claim 18 are not disclosed or taught by Nicholas, we agree with the appellants that the rejection of independent claim 18 and

dependent claims 19, 22, 23 and 26 as being anticipated by Nicholas cannot be sustained.

The Rejections Under Section 103

The test for obviousness is what the combined teachings of the prior art would have suggested to one of ordinary skill in the art. See, for example, In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In establishing a prima facie case of obviousness, it is incumbent upon the examiner to provide a reason why one of ordinary skill in the art would have been led to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. See Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Int. 1985). To this end, the requisite motivation must stem from some teaching, suggestion or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from the appellant's disclosure. See, for example, Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1052, 5 USPQ2d 1434, 1439 (Fed. Cir.), cert. denied, 488 U.S. 825 (1988).

The first of these rejections is that independent claim 1 and dependent claims 5, 6 and 8-11 are unpatentable over Nicholas in view of Meador. The examiner is of the view that Nicholas discloses all of the subject matter recited in claim 1 except for the one-way valve, but that it would have been obvious to one of ordinary skill in the art to

provide such a feature on the proximal end of the Nicholas tubular body in view of the teachings of Meador.

However, we differ with the examiner with regard to what elements of this claim are missing from Nicholas. As we explained above with regard to the Section 102 rejection of claim 18, the presence of the handle on the proximal portion of the Nicholas elongated tubular body causes the reference to fail to disclose or teach that the seal is slidable along the entire length of the tubular body, a feature that is required in claim 1. Moreover, to modify Nicholas to provide such a feature would necessitate removal of the handle which would, from our perspective, render the Nicholas device unsuitable for operating in the intended manner, thus presenting a disincentive to the artisan to make such a change.

With regard to combining the references, Nicholas discloses a luer lock on the proximal end of the elongated tubular body for the purpose of attaching a syringe to inject dye or other substances into the passage in this body (column 9, lines 14-18). There is nothing in the reference to indicate that the luer lock restricts the passage of fluid in either direction, and thus it would appear to allow fluid to be infused or removed through the central passage in the tubular body. Meador discloses a device for flushing the uterus of a sow. The device comprises an elongated tubular member having a squeeze ball 15 for pumping fluid from the proximal to the distal end of the tubular member, and a pair of one-way valves 18 and 19 to prevent back-flow of fluids from the

distal end (column 2). It is the examiner's view that Meador would have suggested to one of ordinary skill in the art the installation of a one-way valve on the proximal end of the Nicholas tubular member "in order to prevent liquid flowing back down from the uterus and to avoid producing air bubbles in the fluid being infused in [sic, into] the uterus" (Answer, page 7).

The mere fact that the prior art structure could be modified does not make such a modification obvious unless the prior art suggests the desirability of doing so. See In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). It is our view that the use of a luer lock by Nicholas indicates that provision for flow in both directions through the tubular member is a feature of the invention. This being the case, modification of the Nicholas system by placing a one-way valve at the proximal end of the tubular member would significantly change its capabilities by limiting flow to only one direction. In addition, when the syringe is in place to inject fluid into the tubular body, fluid is precluded from being discharged therefrom, and thus it would act as a one way valve. The examiner has not provided evidence that the Nicholas system would benefit from the presence of a one way valve at its proximal end, and therefore it appears to us that the only suggestion for doing so is found in the hindsight afforded one who first viewed the appellants' disclosure. This, of course, is not a proper basis for a rejection under Section 103. In re Fritch, 972 F.2d 1260, 1264, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992).

For the reasons provided in the preceding two paragraphs, it is our conclusion that the combined teachings of Nicholas and Meador fail to establish a <u>prima facie</u> case of obviousness with regard to the subject matter recited in independent claim 1, and we therefore will not sustain this rejection of claim 1 or, it follows, of claims 5, 6 and 8-11, which depend therefrom.

Claims 1, 2 and 4 stand rejected as being unpatentable over Swor in view of Meador. As was the case with Nicholas, the examiner has taken the position that the primary reference discloses all of the subject matter recited in claim 1 except for the one-way valve, which would have been obvious in view of Meador. Swor discloses an elongated tubular body 48 having a central passage through which fluids may be delivered to the uterine cervix. A slidable seal 30 is mounted on the tubular body and it appears to be movable over the entire length of the tubular body of the embodiment shown in Figures 1-3, as is required by claim 1. A luer lock 60 is installed on the proximal end of the tubular body so that a syringe 70 can be used to inject fluid into the central passage (column 3, lines 51-61). As was the case with the other prior art rejection of claim 1, the examiner has failed to set forth the suggestion which would have motivated one of ordinary skill in the art to modify the Swor device by replacing the luer lock with a one-way valve, and our own analysis has failed to locate support for such action. We also point out that the positioning of a syringe in the luer lock to inject fluids, or the installation of a cap on the luer lock (Figure 2), would preclude fluid from

exiting through the proximal end of the tubular member, thus eliminating the need for a one way valve.

We therefore agree with the appellants that Swor and Meador fail to establish a <u>prima facie</u> case of obviousness with regard to the subject matter of claims 1, 2 and 4, and we will not sustain this rejection. We reach the same result, for the same reason, with regard to dependent claim 3, which was separately rejected as being unpatentable over Swor and Meador.

Claim 20 stands rejected as being unpatentable over Nicholas. This claim depends from independent claim 18 through dependent claim 19, both of which were rejected as being anticipated by Nicholas. We did not sustain the rejection of claims 18 and 19, and considering Nicholas anew under Section 103 does not alter the fact that Nicholas fails to disclose or teach the seal slidable over the entire length of the tubular body, or the neck positioned at the distal end of the seal, which also are required in claim 18. Nor are we of the opinion that the evidence adduced by the examiner supports the conclusion that it would have been obvious to one of ordinary skill in the art to modify the Nicholas device to alleviate these deficiencies. This being the case, we will not sustain the rejection of claim 20.

The rejection of claim 21, which depends from claim 18, on the basis of Nicholas in view of Swor, also is not sustained. While Swor discloses an elongated tubular body having a tip that is closed and rounded, Swor does not overcome the deficiencies found

in Nicholas with regard to the elements recited in claim 18, which we previously discussed in the Section 102 rejection. In this regard, while in the Swor device the seal is slidable over the entire length of the tubular body, as we pointed out above, to so modify Nicholas would necessitate removal of the handle, which would not be in keeping with its operation. The rejection of claim 21 is not sustained.

With regard to claim 24, which also depends from claim 18, Weber fails to overcome the aforementioned problems with Nicholas regarding the limitations of claim 18, and this rejection cannot be sustained. The same situation leads to the same conclusion with regard to claim 25, which also depends from claim 18 and stands rejected on the basis of Nicholas and Harris.

Claims 27 and 28 each stand separately rejected as being unpatentable over Nicholas. These claims depend from claim 18, and the rejections are not sustained for the same reasons as were expressed above with regard to the rejection of claim 20, which was rejected on the same basis.

Independent claims 12 and 17 each stand separately rejected as being unpatentable over Nicholas in view of Meador. We discussed these references above with regard to the like rejection of claim 1 et al. Claim 12 contains the requirement that the seal be slidable over the entire length of the tubular body and that there be a one-way valve at the proximal end of the tubular member, and claim 17 contains those features plus the limitation that the seal have a neck on its distal end. As we found

above, these limitations would not have been obvious in view of the combined teachings of Nicholas and Meador, and therefore a <u>prima facie</u> case of obviousness is lacking with regard to claims 12 and 17 and we will not sustain their rejections.

CONCLUSION

None of the rejections are sustained.

The decision of the examiner is reversed.

NEAL E. ABRAMS Administrative Patent Judge

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CHARLES E. FRANKFORT Administrative Patent Judge)) BOARD OF PATENT) APPEALS AND) INTERFERENCES)))
JEFFREY V. NASE Administrative Patent Judge)

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